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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/597,102	06/20/2000	Christopher Graham Raphael Parsons	MERZ30 / dln	6038

25666 7590 09/26/2005

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EXAMINER	
JIANG, SHAOJIA A	
ART UNIT	**PAPER NUMBER**
1617	

DATE MAILED: 09/26/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/597,102	PARSONS ET AL.	
	Examiner	Art Unit	
	Shaojia A. Jiang	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 August 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-13 and 15-17* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-13 and 15-17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Applicant's request for reconsideration of the finality of the rejection of the last Office action dated June 1, 2005 in the interview on August 8, 2005, is found persuasive (see the Interview Summary dated August 8, 2005 of record), therefore, the rejection of Claims 1-13 and 15-17 made under 35 U.S.C. 103(a) as being unpatentable over Gold et al. (WO 99/01416) in view of Greenshaw A J, and Ravelli et al. or Sullivan et al. or Wilde et al. of record in the Final Office Action dated June 1, 2005 is withdrawn.

Moreover, Applicant's remarks in the interview with respect to the obviousness-type double patenting rejection over US 6,828,462 of record in the previous Office Action have been fully considered and found persuasive to remove the rejection, since with provision recited in claim 5 of US 6,828,462, the instant compounds are not the same compounds as those in the patent, nor are obvious over those in the patent (see the Interview Summary). Thus, said rejection is withdrawn.

Therefore, **the finality of that action dated June 1, 2005 is withdrawn**. New grounds of rejections set forth below.

Currently, claims 1-13 and 15-17 are pending in this application and examined on the merits herein.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-13 and 15-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gold et al. (WO 99/01416, of record) in view of Lucot ("*Effects of N-methyl-D-aspartate antagonists on different measures of motion sickness in cats*", PTO-892).

Gold et al. discloses that the instant 1-aminoalkylcyclohexanes compounds are NMDA receptor antagonists, and they are known in combination with one or more pharmaceutically-acceptable diluents, excipients, or carriers, to be useful in a pharmaceutical composition and method for treating, eliminating, and alleviating CNS disorders (see abstract and page 3 lines 17-20) or a method of treating a living animal (including a human) for alleviation of a condition which is alleviated by an NMDA receptor antagonist (see claim 12 and page 29 line 24 to page 30 line 12), and other diseases (see page 46 line 20). See also abstract, pages 4-8, 10-20, and claims 1-34 of Gold et al.

Note that Gold et al. discloses the effective amounts of the compound herein in the range of 20 mg to 100 mg/day or 10 mg to 250 mg/day, or 1-1000 mg/day or 50-500 mg/day (see page 29 lines 18-22, page 30 line 5-6), which are within or same as the effective amounts 1-1000 mg/day or 1-500 mg/day, indicated in Applicant's specification (see page 22 the last four lines of the specification).

Further note that the recitation "a condition which is alleviated by a 5HT3 or neuronal nicotinic receptor antagonist" in the claim is considered to be merely a mechanism of the action of the treatment as discussed in the interview. Note it has been

held that a mechanism of action of a treatment would not by itself carry patentable weight if the prior art teaches the same or nearly the same method steps. Thus, Applicant's recitation of a new mechanism of action for the prior art method will not, by itself, distinguish the instant claims over the prior art teaching the same or nearly the same method steps.

Gold et al. does not expressly disclose the employment of the NMDA receptor antagonists, the same active compounds of the formula herein, in a method of treating of the particular disorder or condition such as emesis (also as known vomiting), cerebellar tremor, appetite or irritable bowel syndrome in a living animal.

Lucot teaches that "because N-methyl-D-aspartate (NMDA) antagonists prevent cisplatin-induced emesis and NMDA receptors are in both emetic pathways and structures associated with the final common pathway for vomiting, they have the potential to be broad-spectrum antiemetics." (see abstract in particular). The efficacy and potency of NMDA receptors were evaluated by determining their effects on motion sickness in cats according to Lucot (see Fig.1 and "Results" at page 408). The measures included the number vomiting, the number of symptom points, which reflect activity early in the final common path and the duration of the retch/vomit sequence, which reflects activity late in the path. The results are consistent with a broad spectrum of antiemetic efficacy with at least a part of its action in the early to middle portions of the final common pathway for vomiting (see also Fig.2 and "Discussion" at page 409).

Thus, it is well-known in the art that an NMDA receptor antagonist is useful in treating a specific condition, emesis or vomiting, and that an NMDA receptor antagonist has a broad spectrum of antiemetic efficacy according to Lucot.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to employ the NMDA receptor antagonists of Gold et al., the same active compounds of the formula herein, in a method of treating the particular condition, emesis.

One having ordinary skill in the art at the time the invention was made would have been motivated to employ the NMDA receptor antagonists of Gold et al., the same active compounds of the formula herein, in a method of treating the particular condition, emesis, since the same active compounds herein are known NMDA receptor antagonists and thus are known to be useful in a method of treating a living animal for alleviation of a condition which is alleviated by an NMDA receptor antagonist according to Gold et al. In particular, it is well known in the art that an NMDA receptor antagonist is useful in treating emesis according to Lucot. An NMDA receptor antagonist is known to possess a broad spectrum of antiemetic efficacy or actions.

Therefore, one of ordinary skill in the art would have reasonably expected that the same active compounds of the formula herein being the NMDA receptor antagonists, would have same or substantially same beneficially therapeutic effects and usefulness in a method of treating emesis in a living animal, by administering the same effective amounts of the same compound of Gold et al.

Thus the claimed invention as a whole is clearly prima facie obvious over the combined teachings of the prior art.

In view of the rejections to the pending claims set forth above, no claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Jiang, whose telephone number is (571)272-0627. The examiner can normally be reached on Monday-Friday from 9:00 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, Ph.D., can be reached on (571)272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

S. Anna Jiang, Ph.D.
Primary Examiner
Art Unit 1617
September 15, 2005